

115TH CONGRESS
1ST SESSION

H. R. 4117

To prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 25, 2017

Mr. DOGGETT (for himself, Mr. CUMMINGS, Ms. DeLAURO, Ms. SCHAKOWSKY, Mr. POCAN, Ms. JUDY CHU of California, Mr. CICILLINE, Mr. COHEN, Mr. CONYERS, Mr. ELLISON, Mr. GRIJALVA, Ms. KAPTUR, Mr. KHANNA, Mr. LANGEVIN, Mr. NADLER, Mrs. NAPOLITANO, Mr. O'Rourke, Ms. PINGREE, Ms. CASTOR of Florida, Mr. RASKIN, and Ms. VELÁZQUEZ) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committees on the Judiciary, and Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Competitive Deals Re-
3 sulting in Unleashed Generics and Savings Act of 2017”
4 or the “Competitive DRUGS Act of 2017”.

5 **SEC. 2. CLAWBACK OF RESEARCH AND DEVELOPMENT TAX**

6 **BENEFITS FOR MANUFACTURERS ENGAGING**
7 **IN PAY-FOR-DELAY.**

8 (a) IN GENERAL.—Section 41 of the Internal Rev-
9 enue Code of 1986 is amended by adding at the end the
10 following new subsection:

11 “(i) RECAPTURE.—

12 “(1) IN GENERAL.—If the Federal Trade Com-
13 mission determines under section 27 of the Federal
14 Trade Commission Act that the taxpayer violated
15 section 5 of such Act in connection with the sale of
16 a drug product (as defined in such section), then the
17 tax under this chapter for the taxable year which in-
18 cludes the date of such determination shall be in-
19 creased by the sum of the product for each of the
20 2 relevant years of—

21 “(A) the aggregate decrease in the credits
22 allowed under section 38 for such relevant year
23 which would have resulted solely from reducing
24 to zero any credit determined under this sec-
25 tion, multiplied by

1 “(B) the sales ratio for such drug product
2 for such relevant year.

3 “(2) RELEVANT YEAR.—For purposes of this
4 subsection, the term ‘relevant year’ means, with re-
5 spect to any determination by the Federal Trade
6 Commission described in paragraph (1), a taxable
7 year in which the aggregate decrease in the credits
8 allowed under section 38 which would have resulted
9 solely from reducing to zero any credit determined
10 under this section is one of the two highest such de-
11 creases during the 10-year period ending with the
12 last taxable year that ended before the date of such
13 determination.

14 “(3) SALES RATIO.—For purposes of this sub-
15 section, the term ‘sales ratio’ means, with respect to
16 a drug product sold by a taxpayer in a taxable year,
17 the ratio of—

18 “(A) the revenue from sales of such drug
19 product by such taxpayer during such taxable
20 year, to

21 “(B) the total revenue from sales of all
22 drug products by such taxpayer during such
23 taxable year.

24 “(4) CONSENT DECREES DEEMED TO BE VIOLA-
25 TIONS.—If a taxpayer enters into a consent decree

1 with respect to any proceeding initiated by the Fed-
 2 eral Trade Commission under section 27 of the Fed-
 3 eral Trade Commission Act, such consent decree
 4 shall be treated for purposes of this subsection as if
 5 the Commission had determined under such section
 6 that the taxpayer violated section 5 of such Act in
 7 connection with the sale of the drug product to
 8 which such proceeding relates.

9 “(5) RECAPTURE NOT TAKEN INTO ACCOUNT IN
 10 DETERMINING MAXIMUM PENALTY.—The increase in
 11 tax under this subsection shall not be treated as a
 12 penalty for purposes of section 27(f) of the Federal
 13 Trade Commission Act.”.

14 (b) EFFECTIVE DATE.—The amendment made by
 15 this section shall apply to taxable years ending after the
 16 date of the enactment of this Act.

17 **SEC. 3. DISALLOWANCE OF TAX DEDUCTION FOR CIVIL**
 18 **PENALTIES IN CONNECTION WITH ACTIONS**
 19 **FOR UNLAWFUL COMPENSATION FOR DELAY.**

20 (a) IN GENERAL.—Section 162(f) of the Internal
 21 Revenue Code of 1986 is amended—

22 (1) by striking “for any fine” and inserting
 23 “for—
 24 “(1) any fine”; and

1 (2) by striking the period at the end and insert-
 2 ing “, and”; and

3 (3) by adding at the end the following new
 4 paragraph:

5 “(2) any civil penalties paid or incurred in con-
 6 nection with a judgment in, or settlement of, a pro-
 7 ceeding under section 27 of the Federal Trade Com-
 8 mission Act.”.

9 (b) EFFECTIVE DATE.—The amendments made by
 10 this section shall apply to taxable years ending after the
 11 date of the enactment of this Act.

12 **SEC. 4. UNLAWFUL COMPENSATION FOR DELAY.**

13 (a) IN GENERAL.—The Federal Trade Commission
 14 Act (15 U.S.C. 44 et seq.) is amended by inserting after
 15 section 26 (15 U.S.C. 57c–2) the following:

16 **“SEC. 27. PRESERVING ACCESS TO AFFORDABLE**
 17 **GENERIC.**

18 “(a) IN GENERAL.—

19 “(1) ENFORCEMENT PROCEEDING.—The Com-
 20 mission may initiate a proceeding to enforce the pro-
 21 visions of this section against the parties to any
 22 agreement resolving or settling, on a final or interim
 23 basis, a patent infringement claim, in connection
 24 with the sale of a drug product.

25 “(2) VIOLATION.—

1 “(A) IN GENERAL.—Subject to subpara-
2 graph (B), in such a proceeding, an agreement
3 shall be an unfair method of competition in or
4 affecting commerce and be a violation of section
5 if pursuant to the agreement—

6 “(i) an ANDA filer receives anything
7 of value, including an exclusive or non-ex-
8 clusive license, an agreement regarding the
9 marketing of a product, or any other com-
10 mercial opportunity or benefit; and

11 “(ii) the ANDA filer agrees to limit or
12 forgo research, development, manufac-
13 turing, marketing, or sales of the ANDA
14 product for any period of time.

15 “(B) EXCEPTION.—Subparagraph (A)
16 shall not apply if the parties to such agreement
17 demonstrate by clear and convincing evidence
18 that—

19 “(i) the value described in subpara-
20 graph (A)(i) is compensation solely for
21 other goods or services that the ANDA
22 filer has promised to provide; or

23 “(ii) the procompetitive benefits of the
24 agreement outweigh the anticompetitive ef-
25 fects of the agreement.

1 “(b) LIMITATIONS.—In determining whether the set-
2 tling parties have met their burden under subsection
3 (a)(2)(B), the fact finder may not presume—

4 “(1) that entry of the ANDA product into
5 interstate commerce would not have occurred until
6 the expiration of the relevant patent or statutory ex-
7 clusivity; or

8 “(2) that the agreement’s provision for entry of
9 the ANDA product into interstate commerce prior to
10 the expiration of the relevant patent or statutory ex-
11 clusivity means that the agreement is procom-
12 petitive.

13 “(c) EXCLUSIONS.—Nothing in this section shall pro-
14 hibit a resolution or settlement of a patent infringement
15 claim in which the consideration granted to the ANDA
16 filer as part of the resolution or settlement includes one
17 or more of the following and nothing else:

18 “(1) The right to market the ANDA product in
19 the United States prior to the expiration of—

20 “(A) any patent that is the basis for the
21 patent infringement claim; or

22 “(B) any patent right or other statutory
23 exclusivity that would prevent the marketing of
24 such drug.

1 “(2) A payment, not to exceed \$7,500,000, if
2 based on reasonable litigation expenses.

3 “(3) A covenant not to sue (including any
4 agreement to dismiss) on any claim that the ANDA
5 product infringes a United States patent.

6 “(d) JUDICIAL REVIEW.—

7 “(1) IN GENERAL.—Any party that is subject
8 to a final order of the Commission, issued in an ad-
9 ministrative adjudicative proceeding under the au-
10 thority of subsection (a)(1), may, within 30 days
11 after the issuance of such order, petition for review
12 of such order in—

13 “(A) the United States Court of Appeals
14 for the District of Columbia Circuit; or

15 “(B) the United States Court of Appeals
16 for the circuit in which any party subject to
17 such final order is incorporated on the date that
18 the petition for review is filed.

19 “(2) TREATMENT OF FINDINGS.—In a pro-
20 ceeding for judicial review of a final order of the
21 Commission, the findings of the Commission as to
22 the facts, if supported by evidence, shall be conclu-
23 sive.

24 “(e) CONSTRUCTION.—

1 “(1) ANTITRUST LAWS AND CONSUMER PRO-
2 TECTION LAWS.—Nothing in this section shall be
3 construed to modify, impair, or supersede the oper-
4 ation of—

5 “(A) the antitrust laws as defined in sub-
6 section (a) of the first section of the Clayton
7 Act (15 U.S.C. 12(a)), or any State law sub-
8 stantially similar to any of such antitrust laws;
9 or

10 “(B) section 5 of this Act or any substan-
11 tially similar State law.

12 “(2) CLAIMS AND COUNTERCLAIMS.—Nothing
13 in this section shall modify, impair, or supersede the
14 right of an ANDA filer to assert a claim or counter-
15 claim against any person under any law referred to
16 in paragraph (1).

17 “(f) PENALTIES.—

18 “(1) FORFEITURE.—Each party that violates
19 subsection (a)(2)(A) shall forfeit and pay to the
20 United States a civil penalty sufficient to deter such
21 violation, but in no event greater than 3 times the
22 value received by the party that is reasonably attrib-
23 utable to such violation. Such penalty shall accrue to
24 the United States and may be recovered in a civil
25 action brought by the Commission, in its own name

1 by any of its attorneys designated by it for such pur-
2 pose, in a district court of the United States against
3 any party that commits such violation. In such ac-
4 tions, the United States district courts are empow-
5 ered to grant mandatory injunctions and such other
6 and further equitable relief as the courts determine
7 to be appropriate.

8 “(2) CEASE AND DESIST.—

9 “(A) IN GENERAL.—If the Commission has
10 issued a cease and desist order with respect to
11 a party in an administrative adjudicative pro-
12 ceeding under the authority of subsection
13 (a)(1), an action brought pursuant to para-
14 graph (1) may be commenced against such
15 party at any time before the expiration of 1
16 year after such order becomes final pursuant to
17 section 5(g).

18 “(B) EXCEPTION.—In an action under
19 subparagraph (A), the findings of the Commis-
20 sion as to the material facts in the administra-
21 tive adjudicative proceeding with respect to a
22 violation described in subsection (a)(2)(A) by a
23 party shall be conclusive unless—

24 “(i) the terms of such cease and de-
25 sist order expressly provide that the Com-

1 mission’s findings shall not be conclusive;
2 or

3 “(ii) the order became final by reason
4 of section 5(g)(1), in which case such find-
5 ing shall be conclusive if supported by evi-
6 dence.

7 “(3) CIVIL PENALTY.—In determining the
8 amount of the civil penalty described in this section,
9 the court shall take into account—

10 “(A) the nature, circumstances, extent,
11 and gravity of the violation, including the
12 amount of commerce affected;

13 “(B) with respect to the violator, in addi-
14 tion to the value received, the degree of culpa-
15 bility, any history of violations, the ability to
16 pay, and any effect on the ability to continue
17 doing business; and

18 “(C) other matters that justice requires.

19 “(4) REMEDIES IN ADDITION.—Remedies pro-
20 vided in this subsection are in addition to any other
21 remedy provided by Federal or State law. Nothing in
22 this paragraph shall be construed to affect any au-
23 thority of the Commission under any other provision
24 of law.

25 “(g) DEFINITIONS.—In this section:

1 “(1) AGREEMENT RESOLVING OR SETTling A
2 PATENT INFRINGEMENT CLAIM.—The term ‘agree-
3 ment resolving or settling a patent infringement
4 claim’ includes any agreement that is entered into
5 within 30 days before or after the resolution or the
6 settlement of a patent infringement claim, or any
7 other agreement that can be shown to be contingent
8 upon, to provide a contingent condition for, or to be
9 otherwise related to the resolution or settlement of
10 the claim.

11 “(2) ANDA.—The term ‘ANDA’ means an ab-
12 breviated new drug application filed under section
13 505(j) of the Federal Food, Drug, and Cosmetic Act
14 (21 U.S.C. 355(j)) or a new drug application filed
15 under section 505(b)(2) of the Federal Food, Drug,
16 and Cosmetic Act (21 U.S.C. 355(b)(2)).

17 “(3) ANDA FILER.—The term ‘ANDA filer’
18 means a party that owns or controls an ANDA filed
19 with the Commissioner of Food and Drugs or has
20 the exclusive rights under such ANDA to distribute
21 the ANDA product.

22 “(4) ANDA PRODUCT.—The term ‘ANDA
23 product’ means the product to be manufactured
24 under the ANDA that is the subject of the patent
25 infringement claim.

1 “(5) DRUG PRODUCT.—The term ‘drug prod-
2 uct’ has the meaning given such term in section
3 314.3(b) of title 21, Code of Federal Regulations (or
4 any successor regulation).

5 “(6) NDA.—The term ‘NDA’ means a new
6 drug application filed under section 505(b) of the
7 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
8 355(b)).

9 “(7) PATENT INFRINGEMENT CLAIM.—The
10 term ‘patent infringement claim’ means any allega-
11 tion made to an ANDA filer, whether or not in-
12 cluded in a complaint filed with a court, that the
13 ANDA filer’s ANDA or ANDA product may infringe
14 any of the following held by, or exclusively licensed
15 to, the NDA holder of the drug product:

16 “(A) Any patent.

17 “(B) Any filed patent application.

18 “(C) Any extension, reissue, renewal, divi-
19 sion, continuation, continuation in part, or reex-
20 amination of a patent.

21 “(D) Any patent term restoration, patents
22 of addition, or extensions thereof.

23 “(E) Any other patent interest.

24 “(8) STATUTORY EXCLUSIVITY.—The term
25 ‘statutory exclusivity’ means those prohibitions on

1 the approval of drug applications under clauses (ii)
 2 through (iv) of section 505(c)(3)(E) (5- and 3-year
 3 data exclusivity), section 527 (orphan drug exclu-
 4 sivity), section 505A (pediatric exclusivity), or sec-
 5 tion 505E (qualified infectious disease product ex-
 6 clusivity) of the Federal Food, Drug, and Cosmetic
 7 Act (21 U.S.C. 355(c)(3)(E), 360cc, 355a, 355f).”.

8 (b) APPLICABILITY.—Section 27 of the Federal
 9 Trade Commission Act, as added by this section, shall
 10 apply to any agreement described in section 27(a)(2)(A)
 11 of that Act entered into after June 17, 2013. Section 27(f)
 12 of the Federal Trade Commission Act, as added by this
 13 section, shall apply to agreements entered into on or after
 14 the date of enactment of this Act.

15 **SEC. 5. NOTICE AND CERTIFICATION OF AGREEMENTS.**

16 (a) NOTICE OF ALL AGREEMENTS.—Section
 17 1112(c)(2) of the Medicare Prescription Drug, Improve-
 18 ment, and Modernization Act of 2003 (21 U.S.C. 355
 19 note) is amended by—

20 (1) striking “the Commission the” and insert-
 21 ing the following: “the Commission—

22 “(A) the”;

23 (2) striking the period and inserting “; and”;
 24 and

25 (3) inserting at the end the following:

1 “(B) any other agreement the parties enter
2 into within 30 days after entering into an
3 agreement covered by subsection (a) or (b).”.

4 (b) CERTIFICATION OF AGREEMENTS.—Section 1112
5 of such Act is amended by adding at the end the following:

6 “(d) CERTIFICATION.—The Chief Executive Officer
7 or the company official with primary responsibility for ne-
8 gotiating any agreement under subsection (a) or (b) that
9 is required to be filed under subsection (c) shall execute
10 and file with the Assistant Attorney General and the Com-
11 mission a certification as follows: ‘I declare that the fol-
12 lowing is true, correct, and complete to the best of my
13 knowledge: The materials filed with the Federal Trade
14 Commission and the Department of Justice under section
15 1112 of subtitle B of title XI of the Medicare Prescription
16 Drug, Improvement, and Modernization Act of 2003, with
17 respect to the agreement referenced in this certification—

18 ““(1) represent the complete, final, and exclu-
19 sive agreement between the parties;

20 ““(2) include any ancillary agreements that are
21 contingent upon, provide a contingent condition for,
22 or are otherwise related to, the referenced agree-
23 ment; and

24 ““(3) include written descriptions of any oral
25 agreements, representations, commitments, or prom-

1 ises between the parties that are responsive to sub-
2 section (a) or (b) of such section 1112 and have not
3 been reduced to writing.’”.

4 **SEC. 6. COMMISSION LITIGATION AUTHORITY.**

5 Section 16(a)(2) of the Federal Trade Commission
6 Act (15 U.S.C. 56(a)(2)) is amended—

7 (1) in subparagraph (D), by striking “or” after
8 the semicolon;

9 (2) in subparagraph (E), by inserting “or”
10 after the semicolon; and

11 (3) by inserting after subparagraph (E) the fol-
12 lowing new subparagraph:

13 “(F) under section 27;”.

14 **SEC. 7. STATUTE OF LIMITATIONS.**

15 The Federal Trade Commission shall commence any
16 enforcement proceeding described in section 27 of the
17 Federal Trade Commission Act, as added by section 3, ex-
18 cept for an action described in section 27(f)(2) of such
19 Act, not later than 6 years after the date on which the
20 parties to the agreement file the other agreements under
21 section 1112(c)(2) or the certification required by section
22 1112(d) of the Medicare Prescription Drug Improvement
23 and Modernization Act of 2003 (21 U.S.C. 355 note).

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